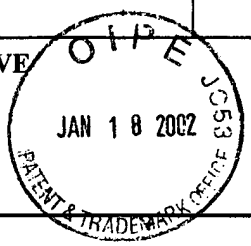
TRANSMITTALLETTER (General - Patent Issued)	Docket No. G1070US2

Patentee(s): **Kenneth W. Batchelor and Stephen V. Frye**

U.S. Patent No.	Issue Date
5,565,467	**October 15, 1996**

Title: **ANDROSTENONEDERIVATIVE**



TO THE COMMISSIONEROF PATENTS AND TRADEMARKS:

Transmitted herewith is:

Declaration of David J. Levy, Ph.D. Under 37 C.F.R. 1.740(b)
Application for Extension of Patent Term under 35 U.S.C. 156
Exhibits 1 through 9

☐ No additional fee is required.
☐ A check in the amount of is attached.
☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **07-1392** as described below. A duplicate copy of this sheet is enclosed.
  ☒ Charge the amount of **$1,120.00**
  ☒ Credit any overpayment.
  ☒ Charge any additional fee required.

Signature

Dated: Jan. 18, 2002

Amy H. Fix, Reg. No. 42,616
Attorney for Applicants
GlaxoSmithKline
Five Moore Drive, PO Box 13398
Research Triangle Park, NC 27709-3398
Telephone: (919) 483-8911
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PATENT TRADEMARK OFFICE

CC:

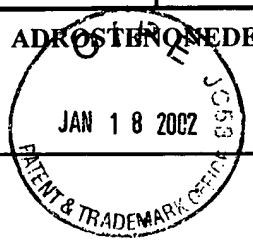
I certify that this document and fee is being deposited on with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Typed or Printed Name of Person Mailing Correspondence

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Batchelor et al.**			Docket No. **G1070US2**
Serial No. **08/405,120**	Filing Date **March 16, 1995**	Examiner	Group Art Unit

Invention: **ADROSTENONE DERIVATIVE**



I hereby certify that this **Application for Extension of Patent Term, Exhibits 1-9, & Declaration**
(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231-0001 on 1/18/02
(Date)

Allyson K. Jacobs
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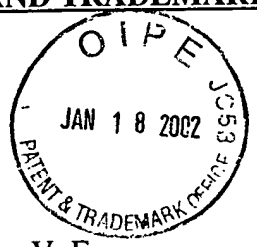


In Re: US Patent No. 5,565,467

Issued: October 15, 1996

Inventors: Kenneth W. Batchelor and Stephen V. Frye

Assignee: SmithKlineBeecham Corporation (formerly Glaxo Wellcome, Inc.)

For: ANDROSTENONE DERIVATIVE

Re: Patent Term Extension for U.S. Patent No. 5,565,467

Commissioner of Patents
Box Patent Extension
Washington DC 20231

Sir:

Applicant, SmithKlineBeecham Corporation, a corporation of the State of Pennsylvania, represents, pursuant to 35 U.S.C. 156(d)(1), that SmithKlineBeecham Corporation, is the record owner and assignee of the entire right title and interest in and to: Letters Patent of the United States of America No. 5,565,467; granted on October 15, 1996 for ANDROSTENONE DERIVATIVE by virtue of an assignment to Glaxo, Inc. dated March 16, 1995, which assignment was recorded in the United States Patent and Trademark Office on March 16, 1995 on Reel 7406, Frame 0967, followed by a Corporate Name Change to Glaxo Wellcome, Inc., followed by a Corporate Merger between Glaxo Wellcome Inc. and SmithKlineBeecham Corporation. A copy of the above-referenced assignment is attached at EXHIBIT 1. A copy of the Corporate Name Change is attached hereto at EXHIBIT 2A. A copy of the Articles of Merger regarding the corporate entity is attached at EXHIBIT 2B.

Applicants further represent, pursuant to 37 C.F.R. 1.785(d), that Applicant is the holder of the regulatory approval granted by the Food and Drug Administration ("FDA") for dutasteride soft gelatin capsules (hereinafter, "DUTASTERIDE"). A copy of the Food and Drug Administration (FDA) Approval Letter for DUTASTERIDE is attached hereto as EXHIBIT 3.

Applicant hereby submits this Application for Extension of Patent Term under 35 U.S.C. 156 by providing the following information pursuant to 37 C.F.R. 1.740. For convenience, the information contained in this application will be presented according to the format set forth in 37 C.F.R. 1.740(a).

[illegible] MKELLEY 00000006 071392 5565467

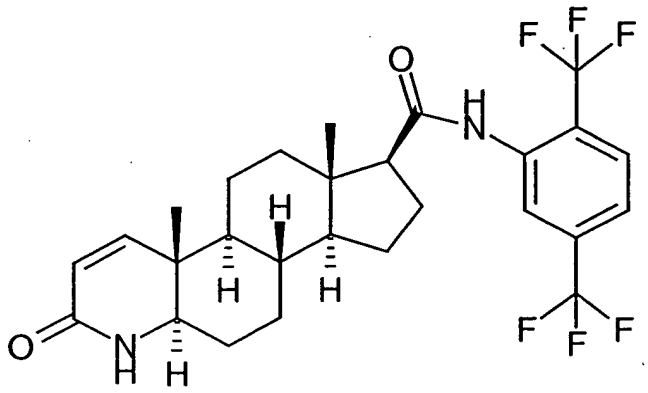
[illegible] 1120.00 CH

(1) This application for patent term extension is based upon the regulatory review period before the FDA, of Applicant's approved product, DUTASTERIDE soft gelatin capsules. The only active ingredient in DUTASTERIDE soft gelatin capsules is dutasteride. A copy of the package insert approved by the FDA as part of New Drug Application 21-319 (NDA) is attached hereto as EXHIBIT 4. Identification of the approved product is provided as follows:

Chemical Name(s): (5α, 17β)-N-{2,5 bis(trifluoromethyl)phenyl}-3-oxo-4-aza- androst-1-ene-17-carboxamide

Molecular formula: $C_{27}H_{30}F_6N_2O_2$

Structural formula:



Molecular weight: 528.5

Physical Form: white to pale yellow powder

(2) The approved product, DUTASTERIDE soft gelatin capsules was subject to regulatory review under the Federal Food, Drug and Cosmetic Act, section 505 (21 U.S.C. 355). See EXHIBIT 3.

(3) DUTASTERIDE soft gelatin capsules received permission for commercial marketing and use under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355) on November 20, 2001. See EXHIBIT 3.

(4) Dutsteride, the only active ingredient in DUTASTERIDE soft gelatin capsules has not been previously approved for commercial marketing or use under the Federal Food Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act.

(5) This application for extension of patent term under 35 U.S.C. 156 is being submitted within the permitted 60-day period, which will expire on January 19, 2002.

(6) The complete identification of the patent for which extension of term is being sought is as follows:

U.S. Pat. No.: 5,565,467

Inventors: Kenneth W. Batchelor and Stephen V. Frye

Assignee: SmithKline Beecham Corporation

For: ANDROSTENONE DERIVATIVE

Issued: October 15, 1996

Expiration Date: October 15, 2013

(7) A complete copy of the patent identified in paragraph (6) above is attached hereto as EXHIBIT 5.

(8) Regarding U.S. Pat. No. 5,565,467:

(a) A petition for correction of inventorship has been filed for this patent.

The patentees, through error without deceptive intent, incorrectly included George F. Dorsey, Jr. and Robert A. Mook, Jr. as inventors. The patentees filed a Petition to Correct Inventorship under 35 U.S.C. §256 and 37 C.F.R. §1.324 and await the Certificate of Correction from the United States Patent and Trademark Office. See EXHIBIT 6.

(b) A maintenance fee payment statement made with respect to U.S. Patent 5,565,467 is attached hereto as EXHIBIT 7.

(c) No reexamination certificate exists in respect of U.S. Patent 5,565,467.

(9) United States Patent 5,565,467 claims the active ingredient, dutasteride, in the approved product, soft gelatin capsules. Applicant hereinbelow lists each applicable patent claim and demonstrates the manner in which each applicable claim reads on the approved product or method of using the approved product.

(a) Claim 1 reads as follows: "17β-N-(2,5-bis(Trifluoromethyl) phenylcarbomoyl-4-aza-5α-androst-1-en-3-one or a pharmaceutically acceptable solvate thereof."

Claim 1 reads on the approved product, DUTASTERIDE soft gelatin capsules, because the active ingredient of the approved product, dutasteride, is 17β-N-(2,5-bis(Trifluoromethyl) phenylcarbomoyl-4-aza-5α-androst-1-en-3-one.

(b) Claim 2 reads as follows: "A pharmaceutical formulation comprising the compound of claim 1 and a pharmaceutically acceptable carrier thereof."

Claim 2 reads on the approved product, DUTASTERIDE soft gelatin capsules, because the approved product is a pharmaceutical composition which contains the active ingredient dutasteride, which is a compound according to claim 1 (*see* item 9(a) *supra*), together with a mixture of mono-di-glycerides of caprylic/capric acid and butylated hydroxytoluene, which are pharmaceutically acceptable carriers.

(c) Claim 3 reads as follows: "A pharmaceutical formulation comprising a safe and effective amount of a compound of claim 1 and a pharmaceutically acceptable carrier thereof."

Claim 3 reads on the approved product, DUTASTERIDE soft gelatin capsules, because the approved product is a pharmaceutical composition which contains a safe and effective amount of the active ingredient dutasteride, which is a compound according to claim 1 (*see* item 9(a) *supra*), together with a mixture of mono-di-glycerides of caprylic/capric acid and butylated hydroxytoluene, which are pharmaceutically acceptable carriers.

(10) The relevant dates and information pursuant to 35 U.S.C 156(g) necessary to enable the Secretary of Health and Human Resources to determine the applicable regulatory review period are as follows:

(a) Effective Dates and Numbers of the INDs
The first Investigational New Drug Application ("IND") for alosetron hydrochloride became effective 24 April 1995; it was designated IND No. 47,838 (GI198745 (5-alpha reductase inhibitor)). See EXHIBIT 8A.

(b) Issue Date of Patent
US Patent No. 5,565,467 issued 15 October 1996 and claims a new drug and drug product. See EXHIBIT 5.

(c) Submission Date and Number of NDA
The NDA for DUTASTERIDE soft gelatin capsules was submitted on 21 December 2000 and was designated NDA No. 21-319. See EXHIBIT 8B.

(d) Approval Date of NDA
NDA No. 21-107 for DUTASTERIDE soft gelatin capsules was approved by the FDA on 20 November 2001. See EXHIBIT 3.

(11) A brief description of the significant activities undertaken by Applicant during both the IND and NDA regulatory periods is presented in a chronological form and is attached hereto as EXHIBIT 8 (including EXHIBITS 8A and 8B), "Due Diligence Log".

(a) The Due Diligence Log reflects significant communications with FDA during regulatory periods. Such communications include, but are not limited to: submission of preclinical reports; registration of clinical protocols and amendments thereof; registration of clinical investigators and amendments thereof; submission of adverse event reports; submission of IND Annual Reports, etc.

(b) Periods between such communications enumerated in the Due Diligence Log reflect Applicant's diligent undertaking of the necessary clinical studies and other activities required by the FDA in order to obtain approval for Applicant's product.

(12) Applicant is of the opinion that U.S. Patent 5,565,467 is eligible for a 769-day extension, up through and including November 20, 2015, taking into account the 14-year limitation under 35 U.S.C. 156(c)(3). See EXHIBIT 9.

(a) Applicant has satisfied the eligibility criteria necessary to obtain a patent term extension pursuant to 35 U.S.C. 156.

(1) 35 U.S.C. 156(a)
U.S. Patent No. 5,565,467 claims a drug product.

(2) 35 U.S.C. 156(a)(1)
The term of U.S. Patent No. 5,565,467 has not expired before the submission of application.

(3) 35 U.S.C. 156(a)(2)
The term of U.S. Patent No. 5,565,467 has never been extended.

(4) 35 U.S.C. 156(a)(3)
The application for extension is submitted by the agent of the owner of record in accordance with the requirements of 35 U.S.C. 156(d) and 37 C.F.R. 1.710 *et seq.*

(5) 35 U.S.C. 156(a)(4)
The approved product, DUTASTERIDE soft gelatin capsules, has been subject to a regulatory review period before its commercial marketing or use.

(6) 35 U.S.C. 156(a)(5)(A)
The commercial marketing or use of the approved product, DUTASTERIDE soft gelatin capsules, after the regulatory review period is the first permitted commercial marketing or use of the approved product under the provisions under which such regulatory review period occurred.

(b) Applicant herewith claims a patent term extension of 769 days, taking into account the 14-year limitation under 35 U.S.C. 156(c)(3), for U.S. Patent No. 5,565,467 pursuant to U.S.C. 156(g) as follows:

(1) One half the IND regulatory review period for the approved product beginning 16 Oct 1996 (the IND period occurring after the date of issuance of U.S. Patent No. 5,565,467) and ending on 20 December 2000 (one day prior to the date on which the NDA for the approved product was initially submitted).

(2) The full term of the NDA regulatory review period commencing 21 December 2000 (the date NDA 21-319 for the approved product was originally submitted) and ending on 20 November 2001 (the date on which NDA 21-319 was approved).

(3) Reducing the sum of Items 12(b)(1) and 12(b)(2) *supra* based upon the 14 year limitation under 35 U.S.C. §156(c)(3).

(4) The total extension applicable for U.S. Patent No. 5,565,467 is equal 769 days. See EXHIBIT 9.

(c) Applicant herewith claims an extension expiry date of **20 November 2015** for U.S. Patent 5,565,467.

(1) The expiration of U.S. Patent 5,565,467 is 15 October 2013.

(2) 35 U.S.C. 156(c)(3) requires that term extensions if necessary be reduced in order to limit the expiration date of a patent receiving term extension to 14 years from the date of NDA approval. The expiration date of U.S. Patent 5,565,467 is therefore limited by the provisions of 35 U.S.C. 156(c)(3). See EXHIBIT 9.

(3) Extending the 15 October 2013 date by 769 days would result in an expiration date of **20 November 2015**. See EXHIBIT 9.

(13) The Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to any determinations to be made relative to the application for extension.

(14) The Commissioner of Patents is hereby authorized to charge deposit account number 07-1392 in the amount of $1,120.00 for receiving and acting upon this application for extension of term. In the event the actual fees due in connection with Applicant's application for patent term extension differ from the amount specified above, the Commissioner is hereby authorized to credit any overpayment or charge any underpayment to Applicants' deposit account number 07-1392.

(15) Inquiries and correspondences relating to this application for patent term extension are to be directed to:

David J. Levy, Ph.D.
Patent Counsel
GlaxoSmithKline
Corporate Intellectual Property Department
Five Moore Drive
Research Triangle Park, NC 27709
(919) 483-2723

b) Applicants submit three original copies of the application papers.

c) Submitted herewith is a Declaration by David J. Levy, Ph.D., Patent Counsel for Glaxo Wellcome Inc., which meets the criteria set forth in 37 CFR 1.740(b), and includes a Rule 3.73(b) certification on behalf of SmithKline Beecham Corporation, which establishes the right of SmithKline Beecham Corporation, as assignee, to take action in the Patent and Trademark Office in connection with this patent, including the naming of Applicant as its agent for purposes of filing this application, and grants power of attorney to the named registered patent attorneys.

I declare further that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of United States Patent 5,565,467 and any extensions thereof.

David S. Levy

January 18, 2002

David J. Levy, Ph. D.
Reg. No. 27,655
Attorney for Applicant
SmithKlineBeecham Corporation

Date

23347

PATENT TRADEMARK OFFICE

The undersigned hereby certifies that this Application for Extension of Patent Term Under 35 U.S.C. 156, including Exhibits 1-9 and supporting papers, is being submitted as triplicate originals.

Respectfully submitted,

By: _____ 11/18/02

David J. Levy, Ph. D.
Reg. No. 27,655
Attorney for Applicant
SmithKlineBeecham Corporation

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re: US Patent No. 5,565,467

Issued: October 15, 1996

Inventors: Kenneth W. Batchelor and Stephen V. Frye

Assignee: SmithKline Beecham Corporation (formerly Glaxo Wellcome Inc.)

For: ANDROSTENONE DERIVATIVE

Re: Patent Term Extension for U.S. Patent No. 5,565,467

Commissioner of Patents
Box Patent Extension
Washington, DC 20231

DECLARATION OF DAVID J. LEVY, PH.D. UNDER 37 C.F.R. 1.740(B)

Sir:

I, David J. Levy, residing in Wake Forest, North Carolina, declare as follows:

(1) I am a patent attorney authorized to practice before the United States Patent and Trademark Office; my registration number is 27,655.

(2) I make this declaration as Patent Counsel for SmithKline Beecham Corporation, a corporation of the State of Pennsylvania, having a place of business at Five Moore Drive, Research Triangle Park, North Carolina, 27709, having general authority to act on its behalf in patent matters.

(3) Pursuant to 37 C.F.R. § 3.73(b) and 35 U.S.C. § 156(d)(1), SmithKline Beecham Corporation is the record owner and assignee of the entire right title and interest in and to US Patent No. 5,565,467 issued October 15, 1996 for ANDROSTENONE DERIVATIVE by virtue of assignment to Glaxo, Inc., recorded in the United States Patent and Trademark Office on March 16, 1995, Reel 7406, Frame 0967; and corporate name change of Glaxo, Inc. to Glaxo Wellcome, Inc.; and subsequent corporate merger between Glaxo Wellcome, Inc. and SmithKline Beecham Corporation, see EXHIBITS 1 and 2 to the above-referenced application.

(4) I have reviewed the evidentiary documents for the aforesaid chain of title and hereby certify pursuant to 37 C.F.R. § 3.73(b) that, to the best of my knowledge and belief, title is in SmithKline Beecham Corporation by virtue of the assignment, corporate name change, and corporate merger noted in paragraph (3).

(5) I have reviewed and understand the contents of the Application submitted herewith on behalf of SmithKline Beecham Corporation, requesting a 769-day extension of the term of US Patent No. 5,565,467.

(6) I believe that US Patent No 5,565,467 is subject to extension pursuant to 37 C.F.R. §1.710.

(7) I believe that a 769-day extension of the term of US Patent No. 5,565,467 is justified under 35 U.S.C. §156 and applicable regulations.

(8) I believe that US Patent No. 5,565,467, for which this extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. 1.720.

(9) Any inquiries and correspondence relating to this Application for Patent Term Extension of US Patent No. 5,565,467 are to be directed to:

David J. Levy, Ph.D.
Intellectual Property Counsel
GlaxoSmithKline
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709-3398
(919) 483-2723
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